

initiated on an antidepressant or antihypertensive medicine. Rather than providing a sample (or starter pack), the GP prescribed a reduced quantity of the chosen medication for dispensing by a community pharmacy. Action research cycles allowed local changes to the initial protocol by study practitioners. Prescription dispensing histories were obtained to track time between starter pack and full quantity dispensing. GP follow-up appointments were tracked via practice appointment systems. Practitioner and patient satisfaction surveys were conducted. **RESULTS:** Two primary care general practices with a pharmacy nearby participated. Thirty-one patients received 32 starter prescriptions. The average age was 43.9 years (SD 16.7, range 23–80) with 44% being male. Twenty-nine starter prescriptions were dispensed with 17 tracked to full prescription dispensing. Thirteen (45%) prescriptions were for antihypertensives. Study prescriptions were always dispensed as a generic brand, whenever one was available. This occurred for 11 (69%) of antidepressants and 3 (23%) of antihypertensives. Twenty-eight patients (87%) made a follow-up appointment, however 11 were outside the time window deemed appropriate for completion of the starter pack. Survey responses showed all patients were satisfied with information provided by their GP and pharmacist, and agreed starter packs facilitate trial of a new medicine (new to the patient, not necessarily new to the market). Patients, GPs and pharmacists approved of the pilot protocol. **CONCLUSIONS:** Community pharmacist involvement in dispensing starter packs was practical and acceptable to practitioners and patients. A similar model could be tailored for other jurisdictions based on local requirements to avoid adverse consequences associated with current systems of prescriber-distributed free prescription medicine samples.

PCV169

ACETYSALICYLIC ACID (ASA) MONOTHERAPY FOR SECONDARY PREVENTION OF CARDIOVASCULAR EVENTS IN PATIENTS WITH PERIPHERAL ARTERIAL DISEASE: AN ASSESSMENT OF THE MEDICAL BENEFIT USING THE IQWiG METHODOLOGICAL APPROACH

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OBJECTIVES: To perform a comparative assessment of the medical benefit of ASA for secondary prevention of cardiovascular events in patients with peripheral arterial disease (PAD) using existing published data. **METHODS:** In a systematic literature search up to January 2009 according to the methodological guidance documents of the IQWiG relevant publications of RCTs and systematic reviews were detected. Study characteristics and results were extracted and presented in evidence tables. **RESULTS:** Overall 16 studies (18 publications) were included in the analyses. The methodological approaches of the studies were heterogeneous and especially the older studies have some major methodological restrictions. There was no statistically significant difference of ASA compared to all other alternatives incl. placebo with regard to overall mortality, risk of myocardial infarction or stroke. A statistically significant disadvantage compared to clopidogrel was shown for vascular mortality and a combined endpoint of vascular mortality, myocardial infarction and stroke. Using this combined endpoint a significant advantage of ASA compared to placebo was shown. With regard to adverse events ASA had a tendency to higher discontinuation rates and a higher incidence of gastrointestinal problems. **CONCLUSIONS:** Overall the analyses using the IQWiG's approach for the assessment of medical benefits showed no advantage of a monotherapy with ASA compared to other alternatives incl. placebo for secondary prevention of cardiovascular events in patients with PAD. The currently available published data do not justify a general recommendation of ASA in PAD patients with regard to cardiovascular endpoints. The analysis shows the need also to assess the benefit of long time used pharmaceuticals to avoid a potential ritualized and inefficient use. Furthermore the results are necessary in the IQWiG's assessments of more innovative technologies to have valid information of standard comparators, too.

PCV170

A CROSS-SECTIONAL ASSESSMENT OF PREVALENCE OF LDLIPID DISORDERS AMONG HUNGARIAN PATIENTS IN PRIMARY CARE

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OBJECTIVES: Elevated low-density lipoprotein cholesterol (LDL-C) is the primary treatment target for patients at risk of coronary heart disease (CHD). Low high-density lipoprotein cholesterol (HDL-C) and elevated triglycerides (TG) are also risk factors for CHD, however often remain unaddressed. This cross-sectional study attempted to identify the extent of prevalence of low HDL-C and/or elevated TG combined with elevated LDL-C among patients treated with lipid modifying therapy (LMT) in Hungary. **METHODS:** Using 8,768 we identified patients who were at least 35 years of age treated with a LMT for at least 6 weeks and also had a complete lipid profile within the past 6 weeks. Patients were considered to be at high CV risk if they had a history of CV disease, or type II diabetes or 10 year CHD risk $\geq 20\%$. Current European Society of Cardiology guidelines were used to define lipid threshold levels. **RESULTS:** In a sample of 1,373 high CV risk patients treated with LMT, slightly over 80% patients experienced ≥ 1 lipid abnormality. Among these, 64% had elevated LDL-C while approximately 37% had elevated LDL-C along with HDL-C and/or TG abnormality. Nearly 33% of treated high risk patient experiencing lipid abnormality had low HDL-C level and 56% experienced elevated TG problem. Approximately 12% of the sample with any lipid abnormality had all 3 lipid abnormalities. **CONCLUSIONS:** In this cross-sectional study of Hungarian high CV risk patients treated primarily with statins, ~80% of all patients with at least one lipid abnormalities

experienced elevated LDL-C. In addition, 45% of treated high CV risk patient still had TG or HDL (or both) lipid abnormalities who could potentially benefit from other lipid-modifying therapies in addition to statins.

PCV171

CRITICAL APPRAISAL OF THE JAPANESE GUIDELINE FOR THE MANAGEMENT OF STROKE

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OBJECTIVES: To assess the first Japanese guideline for the management of stroke developed in 2004 (Int J Stroke 2007; 2: 133–135) by a formal method. **METHODS:** This guideline was critically appraised using three instruments of AGREE, COGS and Shaneyfelt by independent reviewers from the developers. They consisted of 22 stroke physicians, 8 general physicians, and 11 nurses. Best evaluation corresponds to 100% of response rate. **RESULTS:** A response rate was ranging from 66 to 91% with regard to each of many checklists. There was no distinction among the appraisal instruments. Among those, the dimensions of scope/purpose (89%), rigor of development (83%), and clarity/presentation (76%) were highly approved in integrity of the guideline, yet, relatively lower in editorial independence (71%), stakeholder involvement (70%), and applicability (69%). Nurses tended to provide a more favorable response. **CONCLUSIONS:** The Japanese guideline for the management of stroke was first formally evaluated and turned out to be fairly acceptable.

PCV172

TREATMENT PATTERNS AMONG PATIENTS WITH HYPERTENSION: RESULTS OF A US SURVEY

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OBJECTIVES: According to JNC 7 guidelines, most hypertensive patients require multiple drugs—as individual agents or fixed-dose combinations (FDCs)—to achieve blood pressure goals. They suggest that FDCs may be simplest, most convenient, and most cost-effective. However, usage patterns for FDCs are not fully known. Our objective was to explore prescription treatment patterns for monotherapy and combination therapy for US adults with diagnosed hypertension. **METHODS:** Data were obtained from the 2007 US National Health and Wellness Survey (NHWS) quarters 1–3. The NHWS is an annual, nationally representative, Internet-based survey of adults (≥ 18 years). Respondents were asked about their hypertension and its treatment. Drugs reported were compared for monotherapy versus combinations (single agents and/or FDCs) and grouped by class: angiotensin II receptor blockers (ARBs), α - or β -blockers, calcium channel blockers (CCBs), angiotensin-converting enzyme (ACE) inhibitors, and diuretics including hydrochlorothiazide. **RESULTS:** Respondents numbered 19,874. Of 16,495 (83%) who reported using prescription therapy, 215 (1%) responded ambiguously, whereas 7705 (47%) received single-agent monotherapy: an ACE inhibitor (2828 [37%] of 7705), a β -blocker (1796 [23%]), or something else. The remaining 8575 (52% of 16,495) patients received combination therapies: two single agents with no FDC (3516 [41%] of 8575), three or more single agents with no FDC (2285 [27%]), an FDC alone (1517 [18%]), an FDC plus one agent (744 [9%]), an FDC plus two single agents (432 [5%]), or other (81 [1%]). Common FDC-only therapies were an ARB + hydrochlorothiazide (713 [47%] of 1517 patients), and an ACE inhibitor + CCB (384 [25%]). **CONCLUSIONS:** More than half of the hypertensive respondents to the NHWS received at least two antihypertensive agents, with the majority receiving multiple individual products instead of an FDC product. Understanding the factors contributing to this use profile, such as cost, availability, convenience, and compliance, requires further exploration.

GASTROINTESTINAL DISORDERS – Clinical Outcomes Studies

PG11

A RECORD-LINKAGE STUDY OF ADVERSE UPPER GASTRO-INTESTINAL EVENTS WITH NSAIDS IN A UK POPULATION UTILISING DIFFERENT EPIDEMIOLOGICAL DESIGNS TO MINIMISE CONFOUNDING

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OBJECTIVES: The advantage of selective inhibitors of cyclo-oxygenase-2 (COX-2 NSAIDs) over other traditional non-selective NSAIDs (tNSAIDs) is that the risks of serious upper gastro-intestinal events are lower. This study aimed to assess the GI toxicity of tNSAIDs in comparison with COX-2 NSAIDs, comparing different epidemiological designs. **METHODS:** Incident users of NSAIDs in Tayside, Scotland, UK were identified from January 1,2005 to 2007 from the population databases of the Health Informatics Centre. Confounders included age, gender, deprivation, comorbidity and prescribed ulcer healing drugs, and aspirin. Analysis of upper GI hospitalisation utilised standard multiple regression analysis using Cox PH model; adjustment for propensity scores; and the Self Controlled Case Series (SCCS). **RESULTS:** From a total cohort of 68,736 users of NSAIDs, there were 1.5% (n = 982) receiving a COX-2 NSAID, with Celecoxib having the highest proportion 81.5% (n = 800). Differences in baseline characteristics indicated that prescribing of COX-2 NSAIDs was more prevalent in the elderly, those who received aspirin, ulcer healing drugs and with a history of other GI hospitalisations. In the standard adjusted Cox PH model, those in receipt of COX-2 NSAIDs compared with other tNSAIDs had higher risk of upper GI events (HR = 1.95, 95% CI 1.19, 3.17). After adjustment